UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NUMBER 01-11496-RGS

ICN PHOTONICS LIMITED

v.

CYNOSURE, INC. d/b/a/
NEW ENGLAND CYNOSURE, INC.

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF PATENT INVALIDITY

July 15, 2002

STEARNS, D.J.

Plaintiff ICN Photonics Limited (ICN), holds U.S. Patent No. 5,983,900 (the '900 patent ("Wrinkle Removal"), which claims a method of irradiating facial wrinkles with a laser source without causing second degree burns. ICN filed this action against defendant Cynosure, Inc., alleging willful infringement of the '900 patent. Cynosure moves for summary judgment, asserting that the '900 patent is invalid for its failure to meet the "written description" requirement of 35 U.S.C. §§ 112. Because the '900 patent as originally filed failed to "convey with reasonable clarity" that the patentee was "in possession of" the subject matter claimed, Vas-Cath v. Mahurkar, 935 F.2d 1555, 1564 (Fed. Cir. 1991), the motion for summary judgment will be GRANTED.

BACKGROUND

Robert Clement and Michael Kiernan applied to the Patent and Trademark Office (PTO) for the "Wrinkle Removal" patent on August 28, 1997. Their stated objective was

> to provide a method of removing wrinkles from a superficial area of mammalian skin without causing secondary burns and other problems associated with traditional wrinkle removal.

The application contained the following nine claims:

1. A method of cosmetically removing wrinkles from a superficial area of mammalian skin tissue having, in the order specified, an epidermal layer, a basal layer, and a dermal layer, which method comprises:

   irradiating said dermal layer through said basal layer by means of visible or infra-red radiation, said irradiation being selected to be absorbed by a chromophore in said dermal layer such that collagen present in said dermal layer is heated, while said basal layer remains intact so as to substantially inhibit contact of said dermal layer with ambient air.

2. A method according to claim 1, wherein said irradiation is from a coherent radiation source.

3. A method according to claim 2, wherein said source comprises a ruby laser arranged to target the dermis.

4. A method according to claim 2, wherein said source comprises a dye laser of wavelength selected to target oxyhemoglobin present in blood vessels in said dermal layer.

5. A method according to claim 2, wherein said source comprises a dye laser, a ruby laser, or a semiconductor laser which scans said area of mammalian skin tissue.

6. A method according to claim 5, wherein said laser comprising said source is pulsed.

7. A method according to claim 6, wherein said pulsed laser has pulses of duration 10μsec to 10msec.

8. A method according to claim 1, in which said superficial area of mammalian skin tissue is treated with an artificial chromophore which is absorbed into said dermal layer.

9. A method according to claim 8, wherein said artificial chromophore is applied to the epidermal layer in the form of a liposome-containing topical formulation.

Claim 1 is independent, while claims 2 through 9 are dependent. On January 26, 1999, the patent examiner rejected claims 1 and 2 and claims 4 through 9 as anticipated by the prior art. Claim 3 was rejected as unpatentable. In identifying the infirmities of the rejected claims, the examiner stated that certain claims "would be allowable if rewritten to overcome the [indefinite language]." The inventors thereafter amended the application by further describing the basal and dermal layers of the skin as "having blood vessels with blood therein" and inserting in claim 1 the limitation that irradiation occurs "without coagulating the blood in the blood vessels of said basal layer and without coagulating the blood in the in the blood vessels of said dermal layer." The patent was issued in its present form on November 16, 1999. Cynosure contends that the '900 patent application fails to meet the written description requirement of 35 U.S.C. § 112(1), and is thus invalid as a matter of law.

DISCUSSION

A party is entitled to summary judgment when there is no genuine issue of material fact and the party can show that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Perez v. Volvo Car Corp., 247 F.3d 303, 310 (1st Cir. 2001). A "genuine" issue of fact is one that a reasonable trier of fact could resolve in favor of the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-249 (1986). When considering a summary judgment motion, a court must view the evidence presented in the light most favorable to the non-moving party and resolve all doubts in its favor. See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998).

There is a statutory presumption that an issued patent is valid. 35 U.S.C. § 282. Thus, where the question is one of validity, the movant's burden is to demonstrate invalidity

"by clear and convincing evidence." Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH, 139 F.3d 877, 881 (Fed. Cir. 1998).[1]

"The written description requirement reflects the *quid pro quo* of our patent system, in which an inventor is only entitled to claim subject matter that is adequately described to the public." Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 1019 (Fed. Cir. 2002).[2] In TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111 (Fed. Cir. 2001), the Court explained that

> [t]he written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date, . . . the new claims or other added material must find support in the original specification. Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed.Cir.2000) ("The fundamental inquiry is whether the material added by amendment was inherently contained in the original application."); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("[T]he test for sufficiency of support . . . is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.' ") (quoting Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed.Cir.1985)).

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[1]There is a hierarchy of sources that a court consults in construing a patent. On the first rung are the claims, specifications and file history, the "public record . . . on which the public is entitled to rely." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 Fed. Cir. 1995). The patent examiner's decision may also be considered. Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1555 (Fed. Cir. 1985). Extrinsic evidence, such as expert testimony, stands on the lowest rung, and is generally not considered unless the meaning of a technical term is unclear. Vitronics Corp., 90 F.3d at 1583, citing Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995); Markman v. Westview Instruments, Inc., 52 F.3d 967, 980-981 (Fed. Cir. 1995), *aff'd,* 517 U.S. 370 (1996).

[2]The "corollary" of the written description requirement, 35 U.S.C. §§ 132, provides that "[n]o amendment shall introduce new matter into the disclosure of the invention." Thus, an insubstantial description cannot be cured by a subsequent amendment. See Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

Id. at 1118. See also Hyatt v. Boone, 146 F.3d 1348, 1354 (Fed. Cir. 1998) (the specification must "unambiguously describe all limitations" of the claims). While the issue of whether a specification complies with the written description requirement of § 112 is ordinarily a question of fact, a written description can be so deficient as to fail as a matter of law. Regents of the University of California v. Eli Lily & Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997).

Cynosure argues that ICN's original application did not sufficiently disclose the claimed invention, as illustrated by the subsequent amendment of the rejected claims.

> [A]ll of the claims of the plaintiff's asserted patent contain a very specific limitation, added during patent prosecution to try to avoid the prior art, that the claimed method is performed "without coagulating the blood in the blood vessels of said basal layer [of the skin] and without coagulating the blood in the blood vessels of said dermal layer [of the skin]." . . . Given the admitted absence of an express disclosure of the claimed "without coagulating the blood" limitation, the plaintiff's patent could comply with 35 U.S.C. § 112, ¶ 1 only if that limitation was "inherent" in the patent application.

Cynosure Reply, at 3-4. See Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed. Cir. 2000) ("The fundamental inquiry is whether the material added by amendment was inherently contained in the original application."). On this latter point, the parties are in agreement. Where they diverge is over what it means for a limitation to be "inherent." Cynosure argues that the limitation must be "necessarily present," while ICN contends that the specification need only "plausibly support" the limitation.

In Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320 (Fed. Cir. 2000), the Court framed the proper test as one of "immediate discernment" by one skilled in the art.

> In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996). Nonetheless, the disclosure must . . . convey with

> reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir.1994). That inquiry is a factual one and must be assessed on a case-by-case basis. See Vas-Cath, 935 F.2d at 1561 (Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.).

Id. at 1323. In TurboCare, the same panel (again Judge Bryson writing for the Court) stated that

> [i]n order for a disclosure to be inherent, "the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure." Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159, (Fed. Cir. 1998). Brandon's original disclosure is completely lacking in any description of an embodiment in which the spring is located between the casing shoulders and the inner surface of the outer ring portion of the ring segment. Such an embodiment may have been obvious from Brandon's vague reference to a "spring located . . . adjacent to said rings." As we held in Lockwood v. American Airlines, Inc., 107 F.3d 1565 (Fed.Cir.1997), however, that is not enough to satisfy the written description requirement:
>
> > While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

Id. at 1119.

ICN tellingly does not rely on the unvarnished wording of the specification to support its argument that the “anti-coagulation” limitation was inherently disclosed, but rather on the affidavit of Dr. Jeffrey Rapaport, a dermatologist, who is presented as the paradigmatic example of one skilled in the art of laser skin treatment. ICN claims that Dr. Rapaport’s

affidavit pinpoints "the portions of the specification explaining that the coagulation limitation is disclosed to those of skill in the art." See ICN's Surreply, at 14. This seems more a product of wishful thinking than fact. Cynosure captures the essential deficiency in Dr. Rapaport's affidavit in its reply.

> Dr. Rapaport never even purports to opine on the issue presented by this motion: whether the "without coagulating the blood" limitation was necessarily present in the plaintiff's patent application. Although asserting once in passing that something was "inherent" he never explains what he means by this and certainly never says that anything was necessarily present in the patent application when it was filed. His statement that "without causing coagulation is set forth very clearly in" several parts of the patent lacks any factual foundation whatsoever.

Cynosure Reply, at 7.

ICN admits that the '900 patent, as originally filed, failed to specify that its method of wrinkle removal is accomplished without coagulating the blood in the blood vessels of the basal and dermal layers of the skin. Indeed, as Cynosure points out, there was only one unrelated reference to "blood vessels" in the original patent application. ICN insists that because the specification stated that the "basal layer remains intact" and that wrinkles are removed "without damage to the dermis," one skilled in the art (like Dr. Rapaport) would recognize that in applying its method no coagulation of the blood occurs. This simply is not the case. There are any number of reasons why the irradiated basal layer of the skin might remain intact, or the dermis survive scorching, some having to do with absence of coagulation and some not.

This latter point is best illustrated by the Eckhouse Patent No. 5,755, 751 (the patent that led the examiner to initially conclude that the '900 patent was anticipated by prior art). Eckhouse taught a method of treating skin disorders with a pulsed light source that avoided

"burning" or "damage to the skin" by the controlled application of heat, despite the contemporaneous coagulation of the blood. It is far more plausible (to use plaintiff's preferred test) that one skilled in the art would have read the '900 patent application to teach some variation of Eckhouse's method (as the examiner did) rather than the avoidance of coagulation altogether. It is certainly possible that a skilled practitioner might have guessed that it was the absence of coagulation that distinguished the '900 invention, but even informed speculation will not satisfy the notice requirement of § 112. See Hyatt, 146 F.3d at 1353-1354 ("It is 'not a question of whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure. . . . Rather, it is a question whether the application necessarily discloses that particular device.'").

While one might suppose that the inventors, at the time they applied for the '900 patent, knew that their method was accomplished without coagulation, for whatever reason, they omitted that crucial fact in the specification. The omission was fatal.

ORDER

For the foregoing reasons, Cynosure's motion for summary judgment is ALLOWED.

SO ORDERED.

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UNITED STATES DISTRICT JUDGE